IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

No. 5:18-CV-220-FL

ANNIE MCNEIL-WILLIAMS, Plaintiff, v. DEPUY ORTHOPAEDICS, Inc. n/k/a Medical Device Business Services, Inc.; DEPUY SYNTHES PRODUCTS, INC.; JOHNSON & JOHNSON; JOHNSON & JOHNSON SERVICES, INC.; JOHNSON & JOHNSON CONSUMER COMPANIES, Inc. n/k/a Johnson & Johnson Consumer, Inc.; DOE DEFENDANTS 1-100, Defendants.	)	ORDER

This matter is before the court on defendants' motion for summary judgment (DE 28).[1] Also before the court are plaintiff's motion to vacate order staying discovery (DE 27) and motion for discovery (DE 43). These motions have been briefed fully. In this posture, the issues raised are ripe for ruling. For the following reasons, defendants' motion is granted and plaintiff's motions are denied.

STATEMENT OF THE CASE

Plaintiff commenced this products liability action in Harnett County Superior Court, on April 13, 2018, arising out of injuries she allegedly suffered as a result of insertion of a defective knee implant device (the "Product"). Plaintiff allegedly experienced severe pain and discomfort

[1] The court constructively has amended the caption of this order to reflect dismissal by notice of voluntary dismissal previously filed in state court of defendants designated as Zimmer Biomet, Inc., Zimmer Orthopaedic Surgical Products, Inc., Biomet, Inc., Zimmer Biomet Holdings, Inc., and Smith & Nephew, Inc.

following the insertion of the product and underwent a revision surgery due to the failure of the product.

Plaintiff asserts negligence claims against defendants on the basis that they failed to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of the Product. She also asserts defendants failed to exercise due care in the labeling of the Product and failed to issue to consumers and healthcare providers adequate warnings of the risk of serious bodily injury resulting from its use.[2] Plaintiff seeks compensatory and punitive damages, as well as lost wages, disgorgement of profits, restitution, attorneys' fees, interest, and costs.

Defendants removed the case on May 18, 2018, and answered on May 25, 2018. On August 31, 2018, following the parties' submission of individual reports and discovery plans pursuant to Federal Rule of Civil Procedure 26(f), and following a telephonic scheduling conference before a magistrate judge, the court entered case management order allowing defendants to file a summary judgment motion on the ground that all claims are preempted by federal law, and staying discovery pending entry of an order disposing of the motion.

On October 15, 2018, plaintiff filed the instant motion to vacate the court's August 31, 2018, order staying discovery. That same date, defendants filed the instant motion for summary judgment, relying upon a memorandum in support, statement of material facts, and a declaration of Kathy J.

[2] As discussed further herein, plaintiff expressly limits her negligence claims to a theory of breach of duty "to warn and warranty." (Pl's Supp. Br. (DE 48) at 3). While plaintiff asserts nine additional claims apart from negligence in her complaint, plaintiff now specifically "concedes that other claims in Plaintiff's complaint can be dismissed." (Id. at 3 (emphasis added)). Claims apart from negligence asserted in the complaint are: "strict products liability: design defect" (Count II); "strict products liability: failure to warn" (Count III); "breach of express warranty" (Count IV); "breach of implied warranty" (Count V); "fraudulent misrepresentation" (Count VI); "fraudulent concealment" (Count VII); "negligent misrepresentation" (Count VIII); "unjust enrichment" (Count IX); and "unfair and deceptive trade practices" (Count X).

Brocato ("Brocato"), which incorporates and describes business records maintained by defendant DePuy Orthopaedics, Inc. ("DePuy"), including medical records of the Product that is the subject of the instant dispute, and the history of regulation and pre-market approval of the Product by the United States Food and Drug Administration ("FDA").[3]

Plaintiff filed the instant motion for discovery, as corrected, on December 3, 2018, relying upon a memorandum of law, which is identical in substance to her memorandum in opposition to summary judgment, filed separately on November 19, 2018. In support thereof, plaintiff relies upon a declaration by counsel for plaintiff, Margaret E. Cordner ("Cordner"), as well as proposed interrogatories and requests for production of documents. Defendants responded in opposition to the motion for discovery and replied in support of summary judgment.

On March 15, 2019, the court directed the parties to submit supplemental briefing, in light of the decision by the United States Court of Appeals for the Fourth Circuit in Burrell v. Bayer Corp., 918 F.3d 372 (4th Cir. 2019). The parties completed supplemental briefing April 8, 2019.

STATEMENT OF UNDISPUTED FACTS

As pertinent to the instant motion, the undisputed facts may be summarized as follows.[4] In February 2000, defendant DePuy secured FDA approval of the Product, following defendant DePuy's submission to FDA of a PreMarket Approval Application. (Defs' Stmt. of Unidsputed Material Facts ¶ 1; Brocato Decl. ¶¶ 18, 28). Following approval, defendant DePuy submitted to

[3] Defendants Johnson & Johnson, Johnson & Johnson Services, Inc., and Johnson & Johnson Consumer Companies, Inc., assert that they are not appropriately named parties in this case, but appear specially to join in the instant motion for summary judgment. In the event that defendants' motion is not granted, they reserve the right to seek dismissal at a later date, including on the grounds of personal jurisdiction.

[4] Additional facts viewed in the light most favorable to defendants will be addressed in conjunction with analysis of plaintiff's motion for partial summary judgment.

FDA several supplements to the Product, in February and May 2000, July 2007, and February and June 2009. (Defs' Stmt. of Undisputed Material Facts ¶ 2; Brocato Decl., ¶¶ 28-37). On or about April 25, 2013, plaintiff underwent total right knee replacement surgery, during which the Product was implanted. (Defs' Stmt. of Undisputed Material Facts ¶ 3; Brocato Decl., ¶9).

COURT'S DISCUSSION

A. Standard of Review

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the moving party has met its burden, the non-moving party must then "come forward with specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986) (internal quotation omitted).

Only disputes between the parties over facts that might affect the outcome of the case properly preclude entry of summary judgment. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986) (holding that a factual dispute is "material" only if it might affect the outcome of the suit and "genuine" only if there is sufficient evidence for a reasonable jury to return a verdict for the non-moving party). "[A]t the summary judgment stage the [court's] function is not [itself] to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Id. at 249. In determining whether there is a genuine issue for trial, "evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in [non-movant's] favor."

Id. at 255; see United States v. Diebold, Inc., 369 U.S. 654, 655 (1962) ("On summary judgment the inferences to be drawn from the underlying facts contained in [affidavits, attached exhibits, and depositions] must be viewed in the light most favorable to the party opposing the motion.").

Nevertheless, "permissible inferences must still be within the range of reasonable probability, . . . and it is the duty of the court to withdraw the case from the [factfinder] when the necessary inference is so tenuous that it rests merely upon speculation and conjecture." Lovelace v. Sherwin–Williams Co., 681 F.2d 230, 241 (4th Cir. 1982) (quotations omitted). Thus, judgment as a matter of law is warranted where "the verdict in favor of the non-moving party would necessarily be based on speculation and conjecture." Myrick v. Prime Ins. Syndicate, Inc., 395 F.3d 485, 489 (4th Cir. 2005). By contrast, when "the evidence as a whole is susceptible of more than one reasonable inference, a [triable] issue is created," and judgment as a matter of law should be denied. Id. at 489–90.

B. Analysis

Defendants seek summary judgment on the basis that all of plaintiff's claims are preempted by federal law, where it is undisputed that the Product was approved by the FDA. To address the issue raised, the court first sets forth background on preemption law in the context of FDA-approved devices, and then applies that law to the claims plaintiff asserts in this case. Finally, the court addresses plaintiff's motions for discovery.

1. Preemption

The Medical Device Amendments of 1976 (the "MDA") to the Food, Drug, and Cosmetic Act "provides a rigorous, comprehensive, and exclusive framework that precludes state law tort claims that seek to impose different or higher standards upon federally approved devices." Walker

v. Medtronic, Inc., 670 F.3d 569, 578 (4th Cir. 2012). Federally approved devices, for purposes of the instant case, include implantable medical devices that receive "premarket approval" by the FDA. Id. at 547 & 577.

"The premarket approval process includes review of the device's proposed labeling." Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319. "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." Id. "After premarket approval, the devices are subject to reporting requirements," including "to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." Id.

Against this backdrop of rigorous premarket approval, the MDA preempts state law claims in two respects. First, the MDA expressly preempts any state law "requirement . . . which is different from, or in addition to, any requirement applicable under [the MDA] to the device." 21 U.S.C. § 360k(a)(1). The United States Supreme Court has interpreted this provision to mean that "common-law causes of action for negligence and strict liability . . . impose 'requirements' and would be pre-empted by federal requirements specific to a medical device." Riegel, 552 U.S. at 323-24 (quotations omitted). Accordingly, "[s]tate requirements are pre-empted under the MDA only to the extent that they are different from, or in addition to the requirements imposed by federal law."

Id. at 330. The MDA does not expressly preempt state law claims based upon "state duties [that] . . . parallel, rather than add to, federal requirements." Id. (quotations omitted).

Second, the MDA "impliedly" preempts additional types of state law claims. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347 (2001). The statute "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." Id. at 349 n. 4 (citing 21 U.S.C. § 337(a)). Accordingly, state claims not arising from "traditional state tort law which . . . predated the federal enactments in question[]," id. at 353, but rather "solely from the violation of [MDA] requirements," are impliedly preempted because "Congress intended that the MDA be enforced exclusively by the Federal Government," id. at 352.

Although the United States Court of Appeals for the Fourth Circuit has not described the operation of these two preemption doctrines together in a published opinion, other circuit courts have recognized that "[t]hese two types of preemption, operating in tandem, have created . . . a 'narrow gap' for pleadings" in a medical device products liability case. Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1327 (11th Cir. 2017) (quoting In re Medtronic, Inc., 623 F.3d 1200, 1204 (8th Cir. 2010)). "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." Id.

2. Application

Plaintiff's claims fail to escape the foregoing express and implied preemption restrictions in the MDA. In support of her complaint, plaintiff advances primarily a theory of negligence that is based upon breach of a "duty to warn." (Pl's Supp. Mem. (DE 48) at 3-5; Opp. to S.J. (DE 38)

at 10-16). She asserts that the MDA does not preempt her state law negligence claim based upon breach of "the duty to provide the FDA with 'Adverse Reaction' and 'Device Defect reports'" and the duty "to report to the FDA" information suggesting "that a device . . . may have caused or contributed to a death or serious injury." (Opp. to S.J. (DE 38) at 11; see Pl's Supp. Mem. (DE 48) at 4).

Plaintiff's primary asserted theory of negligence liability fails, however, because North Carolina law does not recognize a parallel duty on manufacturers to report to the FDA as plaintiff asserts. Rather, North Carolina law recognizes a duty to warn only users or medical practitioners in certain circumstances. For example, North Carolina law provides a cause of action for "failure to provide adequate warning or instruction," where "[a]fter the product left the control of the manufacturer or seller, the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer." N.C. Gen. Stat. § 99B-5(a)(2).

Consistent with this statute, the North Carolina Supreme Court has recognized a cause of action for failure "to use proper care to give adequate warning to the user, not only as to dangers arising from unsafe design, or other negligence, but also as to dangers inseparable from a properly made product." Corprew v. Geigy Chem. Corp., 271 N.C. 485, 491 (1967) (emphasis added); see Stegall v. Catawba Oil Co. of N. C., 260 N.C. 459, 464 (1963) ("One who supplies directly or through a third person a chattel for another to use, is subject to liability to those whom the supplier should expect to use the chattel . . . if the supplier . . . fails to exercise reasonable care to inform them of its dangerous condition.") (quoting Restatement, Torts, § 388) (emphasis added); see also Smith v. Selco Prod., Inc., 96 N.C. App. 151, 156 (1989) ("A manufacturer must properly inform

users of a product's hazards, uses, and misuses or be liable for injuries resulting therefrom under some circumstances.") (emphasis added).

Plaintiff cites no case, and the court has found none, where North Carolina courts have recognized a duty under North Carolina law to inform the FDA of adverse reactions, defects, and other injury information. Plaintiff cites, instead, to Williams v. Smith & Nephew, Inc., 123 F. Supp. 3d 733 (D. Md. 2015), where the court, applying Maryland law, held that a claimant's "failure to warn claim [was] parallel" to the MDA and thus not preempted. Id. at 742. There, the court noted that "Maryland tort law recognizes that a 'duty to warn can undergird a negligence case in a product liability action,'" and "this duty to warn extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning." Id. (quoting Gourdine v. Crews, 955 A.2d 769, 779 (Md. 2008) and Owens–Illinois, Inc. v. Zenobia, 325 Md. 420, 601 A.2d 633, 646 (1992)). Critically, the court opined that such "reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA," although the court did not cite to any Maryland case law for such proposition. Id. Williams thus is inapposite because it applied Maryland law, not North Carolina law, and it expands such law in a manner not consistent with North Carolina law.

Plaintiff also points to a suggestion by the court in Burrell v. Bayer Corp., 918 F.3d 372 (4th Cir. 2019) that "state-law tort claims predicated on an alleged failure to report adverse events to the FDA" could be "based on an independent state-law duty to warn that could be satisfied by reports to the FDA, running parallel to the defendant's duties under federal law." Id. at 383 n. 4. This statement by the court however is inapposite for two reasons. First, it is made in dicta, because the

court in Burrell addressed only a question of federal subject matter jurisdiction on a motion to remand, leaving for North Carolina courts the determination of federal preemption. Id. at 388.

Second, the case upon which Burrell relies for its "independent state-law duty" proposition is a Ninth Circuit case, Stengel v. Medtronic Inc., 704 F.3d 1224, 1232 (9th Cir. 2013) (en banc), that applied Arizona law. Notably, after Stengel, the Arizona Supreme Court expressly disavowed the reasoning of Stengel on the very proposition that is at issue in this case. See Conklin v. Medtronic, Inc., 431 P.3d 571, 578-79 (Ariz. 2018) ("Because Stengel incorrectly recited and applied Arizona law, we decline to follow it."). The Arizona Supreme Court cogently explained that Arizona law, which is based in part upon the Restatement of Torts, does not recognize an independent state law duty to make adverse event reports to the FDA. Id. at 577-78. This line of cases, at bottom, thus suggests that North Carolina law, which also is based in part on the Restatement of Torts, see Stegall, 260 N.C. at 464, does not recognize an independent state law duty to make adverse event reports to the FDA.

Plaintiff also cites to Carlson v. Bos. Sci. Corp., 856 F.3d 320, 324 (4th Cir. 2017), for the proposition that failure to warn claims under N.C. Gen. Stat. § 99B-5(a) are not preempted. But Carlson does not address preemption in any respect. Rather, it affirms a district court's decision to grant summary judgment to a defendant manufacturer on a failure to warn claim, because the plaintiff had failed to provide evidence that plaintiff or her physician relied upon the allegedly inadequate warning. See 856 F.3d at 324-25. The court assumed, for purposes its holding that the "warnings . . . were inadequate" on the product label in that case, and addressed only the issue of causation. Id. at 324. Thus, on the issues raised by the instant motion, Carlson is inapposite.

Plaintiff suggests, in addition, that she has asserted a negligence claim premised upon breach of a "duty to . . . warranty," in addition to a "duty to warn." (Pl's Supp. Mem. (DE 48) at 3-5; Opp. to S.J. (DE 38) at 10-16). Plaintiff contends that defendants had a duty to "convey an effective warning and warranties." (Pl's Supp. Mem. (DE 48) at 3; Opp. to S.J. (DE 38) at 11) (emphasis added). Plaintiff does not explain, however, how this duty to convey a warranty is any different from a duty to warn, and she suggests that there is no difference by citing only to authorities addressing a duty to warn under North Carolina law. (See id.). Without an articulated basis as to why defendants' asserted breach duty to warranty is different from their asserted duty to warn under North Carolina law, the court is compelled to dismiss such claim, as articulated, on the same preemption basis.

In any event, plaintiff does not assert any warranties that defendants were obligated to convey under North Carolina law that run parallel to MDA requirements, as opposed to different from or in addition to MDA requirements. See Riegel, 552 U.S. at 330. In undertaking premarket approval, FDA "must 'weigh any probably benefit to health from the use of the device against any probable risk of injury or illness from such use.'" Id. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). The FDA "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." Id. "The FDA evaluates safety and effectiveness under the conditions of use set forth on the [product] label, and must determine that the proposed labeling is neither false nor misleading." Id. (citations omitted). Where plaintiff suggests now that defendants were obligated to convey warranties different from what FDA required them to convey in product labeling, such claim is preempted. See id. at 327.

In sum, plaintiff's negligence claims as asserted in the instant matter are expressly and impliedly preempted by the MDA. Therefore, defendants are entitled to judgment as a matter of law on such claims. Furthermore, where plaintiff "concedes that other claims in Plaintiff's complaint can be dismissed," (Pl's Supp. Br. (DE 48) at 3), which concession the court considers under the standard for voluntary dismissal of claims under Rule 41(a)(2), plaintiff's remaining claims are dismissed. Such dismissal is with prejudice because the court determines independently that, as a matter of law, all remaining claims asserted in the complaint are preempted. See, e.g., Riegel, 552 U.S. at 330 (affirming summary judgment of claims "interpreted . . . to assert that [the defendant's] device violated state tort law notwithstanding compliance with the relevant federal requirements"); Walker, 670 F.3d at 581 (holding that products liability claims for negligence, strict liability, and breach of warranty are preempted by the MDA); Buckman, 531 U.S. at 350 (holding that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud"); Thus defendants are entitled to judgment as a matter of law as to all claims asserted in the complaint.

3. Discovery

In her motion to vacate the court's scheduling order and motion for discovery, plaintiff argues she should be allowed a period of discovery on the issue of preemption before the court decides defendants' motion for summary judgment. Plaintiff proposes interrogatories and requests for production related to the design, manufacture, and warnings associated with the Product.

Federal Rule of Civil Procedure 56(d) provides that "[i]f a non-movant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order."

In this case, plaintiff has not demonstrated that discovery is essential to justify her opposition to the motion for summary judgment. The court's preemption determination herein turns upon the simple undisputed fact that the Product is a medical device granted premarket approval by the FDA. See Riegel, 552 U.S. at 317-320 & 330; (Defs' Stmt. of Unidsputed Material Facts ¶ 1; Brocato Decl. ¶¶ 18, 28-37). None of the proposed discovery is directed to this fact, nor does plaintiff assert that additional discovery will provide a basis to dispute this fact. Indeed, the Rule 56(d) declaration of plaintiff's counsel acknowledges "the Product's PMA [premarket approval] and subsequent supplemental approval." (Cordner Decl. ¶ 11).

Rather, plaintiff seeks discovery "that could be used to challenge the integrity of" FDA's premarket approval of the Product. (Id.). For example, plaintiff seeks discovery regarding whether defendants' "submissions to the FDA were timely, truthful and complete." (Id. ¶ 12(e)). Plaintiff seeks information regarding Product development, history, reports and warnings, as well as communications about the device with FDA and healthcare providers. (Id. ¶ 13). A challenge to the integrity of FDA's premarket approval of the Product, however, is itself preempted under Buckman. See 531 U.S. at 349 n. 4 & 350 (stating "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions"; and "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives").

In sum, the discovery sought is inapposite to the court's resolution of defendants' motion for summary judgment. Therefore, plaintiff's motion to vacate and motion for discovery must be denied.

CONCLUSION

Based on the foregoing, defendants' motion for summary judgment (DE 28) is GRANTED. Plaintiff's motion to vacate order staying discovery (DE 27) and motion for discovery (DE 43) are DENIED. The clerk is DIRECTED to close this case.

SO ORDERED, this the 20th day of May, 2019.

LOUISE W. FLANAGAN
United States District Judge